

Decision Memo for Medical Nutrition Therapy Benefit for Diabetes & ESRD (CAG-00097N)

Decision Summary

The following chart outlines the duration and frequency coverage for MNT for both renal disease and diabetes. The only restriction imposed in this decision is regarding the number of hours of basic coverage per year. The referring physician will be free to determine the exact length and number of the visits as long as the yearly limit is not exceeded.

Type of MNT (Any Covered Diagnosis)	Number of Hours Covered per Year ²⁸
Initial MNT	3
Follow-up MNT	2

Pursuant to the exception at 42 CFR 410.32(b)(5), additional hours are considered to be medically necessary and covered if the treating physician determines there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

In addition, if the treating physician determines that receipt of both services is medically necessary, Medicare will cover both DSMT and MNT in initial and subsequent years without decreasing either benefit as long as DSMT and MNT are not provided on the same dates of service.

(The information contained here represents only the first step towards making coverage of these services effective. A manual instruction must be prepared and approved, and the necessary billing and claims processing instructions must be prepared. In addition, changes must be made to bill processing systems in order to allow payment to be made. Consequently, the effective date of service will not be known until the manual instruction has completed the clearance process and been assigned an effective date.)

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Decision Memo

TO: Administrative File CAG: 00097N
Duration and Frequency of the Medical Nutrition Therapy (MNT) Benefit

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RE: Duration and Frequency of the Medical Nutrition Therapy (MNT) Benefit

DATE: February 28, 2002

This memorandum serves three purposes: (1) gives the background for the development of this decision memorandum; (2) summarizes the clinical evidence and analyzes relevant clinical literature on the use of medical nutrition therapy (MNT) for both diabetes and renal disease; and (3) explains the coverage decision regarding the duration and frequency of MNT and the coordination of the benefit with the diabetes self-management training (DSMT) benefit.

I. Background

In 1997, Congress provided coverage for diabetes self-management training under Part B of the Medicare program. Section 4108 of the Balanced Budget Act of 1997, also included a provision that required the Department of Health and Human Services to contract with National Academy of Sciences to examine the benefits and costs associated with extending Medicare coverage for other preventive services including medical nutrition therapy.

As a result of that study, the Institute of Medicine report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly" was published in 2000. The report examined the use of MNT for managing disease in beneficiaries with undernutrition, cardiovascular disease, diabetes mellitus, renal disease, and osteoporosis. It recommended that MNT should be a reimbursable benefit for Medicare beneficiaries.

Effective January 1, 2002, Congress extended Medicare coverage for MNT to beneficiaries with diabetes or a renal disease in section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA). MNT services are defined in statute as "nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional ... pursuant to a referral by a physician..." In the final rule published on November 1, 2001 implementing this statutory provision (66 Fed Reg 55246), CMS established requirements regarding who may perform the service, the payment, and exclusions from coverage. Rather than using the regulatory process, CMS determined that the proper frequency and scope of the MNT benefit could be developed in a more open public forum using the national coverage determination process.

The regulations at 42 CFR 410.132(b)(2), (3), and (5) state:

"(2) A beneficiary may only receive the maximum number of hours covered under the DSMT benefit for both DSMT and MNT during the initial DSMT training period unless additional hours are determined to be medically necessary under the national coverage determination process.

(3) In years when the beneficiary is eligible for MNT and follow-up DSMT, the beneficiary may only receive the maximum number of hours covered under MNT unless additional hours are determined to be medically necessary under the national coverage determination process.

...

(5) An exception to the maximum number of hours in (b)(2), (3), and (4) of this section may be made when the treating physician determines that there is a change of diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care."

Definitions

Medicare coverage for MNT is limited by statute to treatment of beneficiaries with diabetes mellitus or renal disease. Diabetes Mellitus is typically discussed in terms of two types, type 1 and type 2. In the regulation at 42 CFR 410.130, we define diabetes using the definitions of type 1 and type 2 from the Institute of Medicine report and include gestational diabetes.

"Diabetes means diabetes mellitus consisting of two types. Type 1 is an autoimmune disease that destroys the beta cells of the pancreas, leading to insulin deficiency. Type 2 is familial hyperglycemia that occurs primarily in adults but can also occur in children and adolescents. It is caused by an insulin resistance whose etiology is multiple and not totally understood. Gestational diabetes is any degree of glucose intolerance with onset or first recognition during pregnancy. The diagnostic criterion for a diagnosis of diabetes for a fasting glucose tolerance test is greater than or equal to 126 mg/dL."

Renal disease is defined in the Institute of Medicine report as three stages, chronic renal insufficiency, end-stage renal disease, and post-renal transplantation. Since BIPA specifically excludes beneficiaries receiving maintenance dialysis for which payment is made under section 1881 of the Social Security Act in the final regulation (42 CFR 410.130), we define renal disease for the purpose of Medicare coverage as:

"Renal disease means chronic renal insufficiency, end-stage renal disease when dialysis is not received, or the medical condition of a beneficiary for 36 months after kidney transplant."

II. Summary of Evidence

Evidence was obtained related to three distinct topics. The first two parts address the scope of the MNT benefit when the beneficiary has diabetes or renal disease. The last part of this section addresses the time periods when MNT and DSMT will be covered.

When more published data is available, CMS will review the pertinent published studies. In the following, we give a cursory discussion of the published evidence and then discuss the protocols and clinical guidelines upon which we base this decision.

Diabetes Mellitus - Clinical Background

The Centers for Disease Control estimates that there are nearly 16 million people in the United States who have diabetes and 5 million of these people are unaware of their disease. Almost 800,000 new cases are diagnosed each year and approximately 200,000 people die each year as a result of diabetes.¹

The major forms of diabetes are chronic, progressive illnesses that over time can lead to severe complications including blindness, amputation, renal failure, heart disease and stroke. Large scale studies, including the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS), as well as numerous smaller studies have demonstrated that the more closely glucose is controlled, the less rapidly these complications are likely to develop.² Inadequate knowledge and a lack of self-management skills are often cited as causes for patient hospitalizations in these studies. Potentially preventable conditions such as hyperglycemia, hypoglycemia, and diabetic ketoacidosis accounted for 24 percent of emergency room visits by patients with diabetes at one hospital.³

One of the cornerstones of glucose control is dietary management, which emphasizes optimal total caloric intake for weight control and provides calculated meal plans of various nutrients appropriate for glycemic control. Regardless of the type of diabetes or whether the patient requires medication (insulin or oral), adequate understanding of the role diet plays in glucose control is a key element in the treatment of the disease and the prevention of complications.

Evidence for the Duration and Frequency of the MNT Benefit for Beneficiaries with Diabetes

In reviewing the written literature identified in a PubMed (a medical research database) search, we found no clinical trials that described in detail the optimal number and frequency of visits that would produce a beneficial effect for individuals with diabetes.

We found that the dietary protocols developed by the American Dietetic Association are generally accepted by health care providers as representing the standard of treatment for diabetic MNT.⁴ This was confirmed with representatives from the American Diabetes Association and the American Association of Diabetes Educators. To make our recommendation for the question of how much MNT should be covered for beneficiaries with diabetes, we relied on nationally recognized protocols. As noted earlier, consideration of protocols established by dietitian or nutrition professional organizations is in accordance with §1861(s)(2)(V)(iii) of the Social Security Act.

While there are some minor variations between the various protocols, the components of diabetic MNT in the year of initial diagnosis include initial and follow-up visits. Protocols call for 4 visits during an episode of care with time between visits ranging between 2- 4 weeks initially to 6-12 months towards the end of the care. If the MNT regimen is matched to the clinical regimen for physicians, the visits would occur at least on a quarterly basis once the individualized dietary plan is developed. The time suggested for the visits are stated in ranges.

First Year of MNT Benefit	American Dietetic Association
1	60 - 90 minutes
2	30 - 45 minutes
3	30 - 45 minutes
4	30 - 45 minutes
Subsequent Years of MNT Benefit	
Per year	1-2 visits

Also, significant changes in diagnosis, condition, or treatment regimens could result in dietary changes that may require additional hours of coverage under 42 CFR 140.132(b)(5).

Renal Disease - Clinical Background

Chronic renal failure (CRF) is a significant cause of morbidity and mortality in the United States.⁵ In 2000, there were over 270,000 patients on dialysis and over 14,000 kidney transplants.⁶ Symptoms of CRF result largely from an accumulation of substances like creatinine, urea and potassium that are usually excreted in the urine and include lethargy, confusion, irregular heart beats, nausea, vomiting and many others.⁷

"Chronic renal insufficiency" as defined in 42 CFR 410.130, means the stage of renal disease associated with a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate [GFR] 13-50 ml/min/1.73m²). It is at this stage that interventions are often initiated in attempts to prevent progression of the renal disease. Interventions have targeted dietary protein restriction and control of hypertension and diabetes mellitus.⁸ This decision will provide policy for individuals who suffer from chronic renal insufficiency or end-stage renal disease when dialysis is not used, and/or post-transplantation patients.

Evidence for the Duration and Frequency of the MNT Benefit for Beneficiaries with Renal Disease

A Medline (a medical research database) search using keywords "nutrition" and "kidney" found one published article. In 1995, Dolecek and colleagues reported the results of a descriptive study that evaluated time expended by registered dietitians during the Modification of Diet in Renal Disease (MDRD) Study.⁹ The authors reviewed dietitian records over the period of the study and categorized time spent by dietitians into preparation time, direct counseling time, charting time, and others. They found that the mean direct counseling time of visits decreased during the follow-up period, ranging from 68 minutes in the first 4 months to 36 minutes in months 25-36 for patients in the low-protein diet group. In this study, there were no direct comparisons of amount of counseling time to any outcomes or the type of interventions used. To show better outcomes from varying amounts of time or frequency of visits, we would have expected comparisons of different amounts of times for different groups of subjects resulting in a stabilization of the GFR.

Consideration of protocols established by dietitian or nutrition professional organizations is in accordance with §1861(s)(2)(V)(iii) of the Social Security Act. In accordance with the statute, we considered the following information in our deliberations.

The American Dietetic Association provided their guidelines and recommended 6 visits (5.5 hours) the first year and 4 visits (3 hours) in subsequent years. We also received protocols from the National Kidney Foundation. A summary comparing the protocols is shown below.

First Year of MNT Benefit	National Kidney Foundation	American Dietetic Association
first visit	90 minutes	60-90 minutes
second visit	30-60 minutes	45-60 minutes
third visit	30-60 minutes	30-45 minutes
Subsequent visits	30-60 minutes	30-45 minutes
Subsequent Years of MNT Benefit		
Per year		1-2 visits

In a letter to CMS, the National Kidney Foundation recommended that the "frequency of visits should be a minimum of 5 per year to a maximum of 12 per year."¹⁰ This range of visits was based on the National Kidney Foundation's clinical practice guideline.

Again, significant changes in diagnosis, condition, or treatment regimens could result in dietary changes that may require additional hours of coverage under 42 CFR 140.132(b)(5).

Evidence for Coverage of MNT for Beneficiaries Who Have Received DSMT During the Same Time Period

Section 1861(s)(2)(V) of the Social Security Act, as amended by BIPA, provides that medical nutrition therapy services are available to a beneficiary "who has not received diabetes outpatient self-management training services within a time period determined by the Secretary..." In the proposed rule, we proposed that the time period would be defined by the time period allowed for completion of initial DSMT (66 Fed Reg 40372, 40405). Initial training consists of 10 hours of education that must be furnished within a continuous 12-month period.¹¹ Therefore, it was proposed that initial MNT training not be allowed within that 12-month period.

In response to the proposed rule and as part of the development of the national coverage determination for the duration and frequency of MNT, we consulted extensively with the American Dietetic Association, American Diabetes Association, and the American Association of Diabetes Educators on this issue. They informed us that the nutrition counseling in the DSMT benefit is different from the nutrition counseling in the MNT benefit. They provided us with expert evidence that the individual MNT nutrition counseling provides a different approach that, when combined with the DSMT group counseling, would result in better outcomes. The DSMT benefit consists of ten different functional areas of which nutritional counseling is only one. The intent of DSMT is to provide overall guidance related to all aspects of the disease designed to increase the patient's knowledge about the disease and how they can exercise control over their own health. MNT is a more intensive nutritional counseling and therapy regimen that relies heavily on follow-up and feedback to the patient to change their behavior over a period of time.

III. CMS Analysis

The final rule provides that the duration and frequency of the MNT benefit would be established through our NCD process. This decision memorandum will use the term "basic coverage" to describe the amount of services for beneficiaries with diabetes and/or renal disease. The final rule also allows "additional hours of coverage" if the treating physician determines that there is a change of diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care.¹²

Diabetes Mellitus

As noted in the evidence section of the document, no published articles supported a specific number of hours that should be covered each year. In the absence of published study results, we relied on generally accepted protocols. The American Dietetic Association protocols used for this analysis were published by Monk.¹³

In general, the visits identified under the evidence section of this document suggest that their should be a total of 3 hours of basic coverage in the year of diagnosis. An episode of care would typically include 1 hour of initial assessment and four 30-minute follow-up interventions during the first year.¹⁴ This is true regardless of the type of diabetes. In subsequent years, the protocols recommended quarterly visits and support a basic coverage in subsequent years of 2 hours.¹⁵

Pursuant to the exception in 42 CFR 410.132(b)(5), additional hours are covered if the treating physician determines there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during the episode of care. Examples of changes in medical condition, diagnosis, or treatment regimen that may be significant enough to require a change in MNT include but are not limited to:

- A beneficiary converting from oral medication to insulin,
- A gestational diabetic requiring frequent dietary modification, and/or
- A beneficiary experiencing a diabetic complication that requires tighter dietary control.

Renal Disease

Similarly, with the absence of published literature on the frequency and duration of MNT in renal disease, we relied on protocols published by the American Dietetic Association when determining the number of hours for basic coverage. In studies of nutrition and kidney disease, the number of visits ranged from 2 total visits to monthly visits, as described in the previous section.

In general, this evidence supports 3 hours of basic coverage of MNT (for example, 1 hour for an initial visit and four 30 minute follow-up visits). In subsequent years, Medicare will cover 2 hours per year for beneficiaries with renal disease. Pursuant to the exception at 42 CFR 410.32(b)(5), additional hours are covered if the treating physician determines there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during the episode of care. Examples of changes in medical condition, diagnosis, or treatment regiment that may be significant enough to require a change in MNT include but are not limited to:

- A beneficiary experiencing a clinically significant decrease in renal efficiency,
- A beneficiary demonstrating a lack of understanding of the renal diet,
- A beneficiary experiencing malnutrition, and/or
- A beneficiary that has completed DSMT demonstrating a need for MNT to address their renal condition in the same episode of care.

The basic hours allowed and the additional hours available under this exception, should provide adequate coverage for all beneficiaries. This flexibility in the benefit structure allows the treating physician to determine the exact amount of the service needed by the beneficiary.

Coverage of MNT and DSMT During the Same Time Period

In the absence of published studies that address the coverage question for duration and frequency of diabetic MNT, we reviewed the published protocols of the American Dietetic Association. Those protocols do not provide guidance for the question of coverage of MNT and DSMT during the same time period. We analyzed this issue by comparing the MNT protocols and the DSMT curriculum that are part of the National Standards for Diabetes Self-Management Education Program (the only standards currently being used by a national accreditation organization for the DSMT benefit) and the behavior modification techniques that are typically used for each service.

The MNT protocols prescribe that the following occur:

1. An initial assessment by a dietitian of the newly diagnosed diabetic patient. This includes assessment of the patient's knowledge of the etiology of diabetes, the impact of diet on his disease, his diet history and food preferences, weight and blood glucose status, caloric, exercise and education needs, and the setting of goals for behavior modification and glycemic and weight control.
2. Compliance with previously set goals is assessed at a relatively early follow-up visit.
3. Subsequent visits should generally be scheduled on a quarterly basis, often coinciding with follow-up visits to the attending physician.²¹

In reviewing how the ten national standards compared to the MNT protocols, we used an article by Peeples, et. al. (2001) that classifies the ten national standards for diabetes self-management education into seven domains. In the following chart we compare the behavior and clinical aspects of initial DSMT as described by Peeples, et.al. (2001) to descriptions of the MNT protocols by Monk (1995). Since these are not identical benefits, the individual components do not match completely. Therefore, each column should be taken as a whole in comparing the two benefits.

Comparison of DSMT and MNT Services

<i>DSMT</i>	<i>MNT</i>
Assessment of current eating behavior including timing of food, meal preparation, missing or skipping planned food, high-fat food intake, overeating behaviors.	Assessment: Biochemical parameters,, weight blood pressure, lifestyle/psychosocial/nutrition history, exercise pattern.
Individualized meal plan	Intervention: Self-management training: nutrition prescription, meal planning, signs symptoms, and treatment of hypo/hyperglycemia, self-monitoring of blood glucose, sick-day management, exercise recommendation, food/drug interaction. Food records to be kept. Follow-up interventions follow the same pattern.
BMI calculated	Client interview: part of assessment.
Lipids, blood pressure, HbA1c	Obtain referral data: labs, medical history, insulin regimen and other medications, exercise limitations/medical clearance.
Goal Setting	Client goals (part of initial assessment) MD's goals.
Behavior-change strategies	Self-management training (part of intervention), grocery shopping, food labeling, expanding food choices, eating out
Periodic reassessment ²²	An assessment takes place at each intervention.
Follow-up ²³	Follow-up Interventions are listed each as a separate intervention in the MNT protocols.
Physician Update ²⁴	Communication: Summary to the treating physician and phone calls to the beneficiary.

A comparison of the curriculum of a DSMT program and the MNT protocols showed that the initial assessment and training for both benefits covered similar topics, though the MNT assessment was more in-depth. A major difference is that the individual nature of the MNT benefit allows the provider to relate the individual meal plan to management of the disease process. Also, the DSMT program curriculum does not specify specific follow-up guidance and feedback as required by the MNT protocols.

CMS then reviewed the expert advice obtained regarding the impact of the DSMT and MNT benefits on beneficiaries. In group sessions, beneficiaries have the advantage of interactions with other diabetics and can learn additional coping skills based on other's experiences.²⁵ Beneficiaries receive reinforcement from a peer group.²⁶ The group session provides a good classroom learning experience for the individual to receive the basic knowledge about diabetes and how changing their own behavior can delay serious complications from the disease. From a different perspective, individualization, feedback, and reinforcement are considered "high quality", effective educational methods.²⁷ The individual sessions provided under the MNT benefit have the advantage of providing more intensive individual attention that may result in a better understanding of the dietary plan and provide the opportunity for the dietitian/nutritionist to provide repeated reinforcement over a period of time to assure the beneficiary's compliance. Because the two benefits provide different behavioral modification techniques (i.e. classroom study for basic knowledge and individual attention that focuses on results over time) which may prove to be complementary, CMS will cover both DSMT and MNT up to their specified limits in the initial year. However, in conformance with the statute, Medicare will not cover DSMT and MNT services that are billed for the same date of service so that beneficiaries may receive the effect of reinforcement over a period of time.

Also, for follow-up DSMT, there is no information to demonstrate that nutrition therapy would necessarily be the topic of follow-up DSMT. CMS' regulations and instructions do not require that nutrition be a part of DSMT follow-up services. Advice from the American Diabetes Association and the American Association of Diabetes Educators indicates that follow-up training for other standard DSMT topics such as adjustment in medications, the use of insulin-pumps, or footcare may be the most frequently discussed subjects. This information indicates that provision of both benefits may be more medically effective for some beneficiaries than receipt of just one of the benefits. CMS will rely on the referring physician to determine if a beneficiary has a medical need for both DSMT and MNT in the same year for follow-up services. However, Medicare will not cover follow-up DSMT and follow-up MNT performed on the same day of service to assure beneficiaries receive the largest possible value from the training.

V. Conclusion

The following chart outlines the duration and frequency coverage for MNT for both renal disease and diabetes. The only restriction imposed in this decision is regarding the number of hours of basic coverage per year. The referring physician will be free to determine the exact length and number of the visits as long as the yearly limit is not exceeded.

Type of MNT (Any Covered Diagnosis)	Number of Hours Covered per Year ²⁸
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(The information contained here represents only the first step towards making coverage of these services effective. A manual instruction must be prepared and approved, and the necessary billing and claims processing instructions must be prepared. In addition, changes must be made to bill processing systems in order to allow payment to be made. Consequently, the effective date of service will not be known until the manual instruction has completed the clearance process and been assigned an effective date.)

¹ Centers for Disease Control, 1997.

² DCCT Research Group, 1993.
UK Prospective Diabetes Study Group, 1991.

³ Clement, 1995.

⁴ Monk, et. al, 1995.

⁵ Rahman and Smith. 1998.

⁶ CMS, 2000.

⁷ Isselbacher, 1994.

⁸ Hall, 2001.

⁹ Dolecek, 1995.

¹⁰ Lambert, 2001.

¹¹ 65 Federal Register 83130, 83149 (December 29, 2000).

¹² Ibid.

¹³ Monk, et. al, 1995.

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Dolecek, 1995

¹⁷ Levey, 1996

¹⁸ Pedrini, 1996

¹⁹ Kasiske, 1998

²⁰ Lambert, 2001

²¹ Monk, et. al., 1995.

²² This is part of Standard 8 of the National Standards that also includes individualized assessment and development of a plan.

²³ This is part of Standard 9 of the National Standards that reads, "There shall be documentation of the individual's assessment, education plan, intervention, evaluation, and follow-up in the permanent confidential education record. Documentation also will provide evidence of collaboration among instructional staff, providers, and referral sources."

²⁴ Although not included in the National Standards, communication with the referring provider is a part of the HCFA Quality Standards as stated in 42 CFR 410.144(a)(7)(v).

²⁵ Wilson and Pratt, 1987.

²⁶ Levy, 1979.

²⁷ Mullen, et.al., 1985.

²⁸ For initial training, a 12-month period is used to match the episode of care to the initial DSMT period. In follow-up years, "per year" means a calendar year.

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